

### **REMARKS**

Applicants respectfully request that prior to further substantive examination the foregoing amendments and the following remarks be made of record in the instant case. This paper is filed in response to an office action mailed March 22, 2006. A response is due August 22, 2006, by virtue of the attached petition and fee for a two-month extension of time. No other fees are believed to be due with the filing of this document, however, should any fees be deemed necessary the Commissioner is authorized to deduct the fees from our Deposit Account No. 13-2855. A duplicate copy of this paper is enclosed.

#### **A. Status of Claims**

Claims 1-52 were pending in the application upon examination and were variously rejected under 35 U.S.C. 101, 112, first and second paragraphs and under 35 U.S.C. 102(b)/103. The rejections are respectfully traversed. Moreover, claims 1-52 have been cancelled and new claims 53-78 are presented. Each of the new claims are directed to methods of treatment of psoriasis, mesothelioma or lung adenocarcinoma using Z glycoalkaloid compositions. The new claims are supported by the application as filed and the original claims. For specific support for the methods of treatment claims, the applicants refer to the specification examples on pages 17-19 and the original claims.

#### **B. Rejections under 35 U.S.C. §101 and 35 U.S.C §112, second paragraph should be withdrawn in view of the new claims**

The Examiner rejected claims 1, 20-22, 27 and 31 for failure to comply with 35 U.S.C. §101 in that the claims recited a use without setting forth steps involved in the process. In addition, the claims 1-52 were rejected for indefiniteness for reciting the term "R3 is . . . a carbohydrate derivative" and for reciting the phrases "such as" and "e.g." The applicants present herewith new claims 53 to 78 in which each of the foregoing issues relating to indefiniteness and non-statutory use language have been addressed.

Original claims 2-52 also were rejected as indefinite as allegedly failing to define "Z Glycoalkaloid." Applicants respectfully disagree with the Examiner, the term "Z glycoalkaloid was originally defined in the claim 1 according to Formula I. As such,

applicants believe no further definition of "Z glycoalkaloid" is necessary in claims that depended from claim 1. The same language has been employed in the new claims.

In view of the above comments, Applicants respectfully request that the rejections under 35 U.S.C. §101 and 35 U.S.C. §112, second paragraph be withdrawn.

**C. Rejections under 35 U.S.C. §112, first paragraph should be withdrawn**

The Examiner rejected the original method of treatment claims 20-27 and 31-36 under 35 U.S.C. §112, first paragraph for assertedly lacking enablement over the full scope of the claims. The Examiner admitted that the specification was enabling for treatment of psoriasis, as treatment of that condition was expressly exemplified in the specification. However, the Examiner cited the various factors in support of the position that the specification is not enabling for the treatment of other diseases.

Initially, while Applicants traverse the rejection, applicants have provided an amended set of claims in which there is claimed a method for the treatment of psoriasis.

In addition, Applicants also provide claims directed to treatment of a disorder selected from mesothelioma and lung adenocarcinoma. Referring to the specification at page 17, it can clearly be seen that the Z glycoalkaloid compositions (SBP 002) used in the invention were toxic to mesothelioma cells and that IL-6 production in mesothelioma cells was reduced as compared to conventional chemotherapy (see page 18). With respect to support for treatment of lung adenocarcinoma, the applicants refer to Example 1 (see page 16) where it is shown that A549 are sensitive to treatment with glycoalkaloid compositions. A549 cells are lung adenocarcinoma cells.

Given the above teachings, applicants submit there are working examples in the specification that support the treatment of psoriasis, mesothelioma and lung adenocarcinoma. In view of the above remarks and amendments, applicants respectfully request that the rejection based on 35 U.S.C. §112, first paragraph for lack of enablement be withdrawn.

**D. Rejections under 35 U.S.C. §102/103 should be withdrawn**

Citing WO 91/10743 or WO 00/61153, the Examiner asserted that claims 4-22 and 27-52 were either anticipated under 35 U.S.C. §102(b) or rendered obvious under 35 U.S.C. §103. More particularly, the Examiner asserted that the aforementioned international patent publications disclosed methods of treating cancer and removal of pathogenic organisms with glycoalkaloids and that the differences between the claimed methods and those of the international applications were minor in nature. Applicants respectfully traverse.

The claims presented above are directed to methods of treating psoriasis and to methods of treating mesothelioma. Nowhere in either WO 91/10743 or WO 00/61153 is there any mention of treatment of either psoriasis or treatment of mesothelioma using compositions that comprise Z glycoalkaloids. In the absence of such a teaching the claims of the present application are not anticipated by the cited publications.

Moreover, the claims also are not rendered obvious by the cited publications. Not only is there no mention of either disorder in the cited publications, one of the publications explicitly states that "Different diseases require different treatments – a treatment effective against skin cancer is unlikely to be as effective against, for example, ovarian cancer as the malignant cells have different receptors." (WO 91/10743, ¶¶ bridging pages 8-9). The only cancers expressly discussed in that document are ovarian cancer and skin cancer. Thus, given that the art cited itself notes that effectiveness of a given regimen will vary from one cancer type to another, there is no expectation that treatment methods for ovarian cancer also would be effective for treatment of psoriasis or mesothelioma. In the absence of such a suggestion, the claims of the present invention cannot be rendered obvious by the cited art.

In view of the above amendments and remarks, Applicants submit that the claims as presented above are novel and non-obvious. Applicants respectfully request that the rejections based on WO 91/10743 or WO 00/61153 be withdrawn.

#### **E. Conclusions**

The applicants present hereinabove a new set of claims directed to treatment of psoriasis and mesothelioma. Treatment of these conditions with the glycoalkaloids as

claimed is nowhere taught in the cited art. Moreover, the methods of treatment of a subject having such a condition are enabled by the express teachings of the specification. The new claims as presented comply with the requirements of 35 U.S.C. §101 in that they recite a use with express process step. As such, applicants believe the claims as presented above overcome all of the outstanding rejections and as such applicants respectfully request reconsideration and allowance of the application.

The Examiner is invited to contact the undersigned at the telephone number listed below if there are any questions with respect to this submission.

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Respectfully submitted,

By 

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